

MAR 14 2014

K134052
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510(k) SUMMARY

ProTom Radiance 330™ Proton Beam Therapy System

**Submitter's Name, Address, Telephone Number, Contact Person
and Date Prepared**

ProTom International Inc.
1100 Parker Square, Suite 230
Flower Mound, Texas 75028

Telephone: 972 410 3551
Facsimile: 972 534 1299

Contact Person: Cheryl Smith

Date Prepared: October 18, 2013

Name of Device Name/Address of Sponsor

Radiance 330™ Proton Beam Therapy System

Name/Address of Sponsor

ProTom International Inc.
1100 Parker Square, Suite 230
Flower Mound, Texas 75028

Common or Usual Name

Proton beam therapy systems

Classification Name

Medical Charged-Particle Radiation Therapy System, 21 CFR 892.5050, Product Code LHN

Predicate Devices

Ion Beam Applications Proton Therapy System with PPBS (K082416)
Hitachi Ltd.'s PROBEAT with DSSS (K073059)
Loma Linda Optivus Technology Proton Beam Therapy System (K992414)

Intended Use

The ProTom Radiance 330 is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.

Technological Characteristics

The Radiance 330 consists primarily of Beam Delivery and Beam Production systems. These systems are comprised of various components and/or accessories designed to produce and deliver a proton beam appropriate for patient treatment. The system components include:

- **Beam Production System.** This system produces the proton beam and directs it to the appropriate treatment room and is comprised of the following subsystems:
 - **Synchrotron subsystem.** The accelerator unit is the source of the proton beam and is composed of the injector (which generates the proton beam) and the synchrotron (which accumulates, accelerates, and extracts the proton beam).
 - **Beam Transport subsystem.** This subsystem guides the proton beam extracted from the synchrotron to the treatment room.
- **Beam Delivery System.** This system controls the irradiation dose and shapes the proton beam supplied through the beam transportation system into the configuration required for patient treatment, and directs the beam appropriately. It is comprised of the following subsystems:
 - **Scan/Dose subsystem**
 - **Gantry subsystem**
 - **Patient Positioning subsystem.**
 - **Treatment Delivery Control subsystem**

Performance Data

Each individual subsystem of the Radiance 330™ was verified and validated, and full system verification and validation was also performed. Beam performance testing to validate complete system integration under nominal and non-nominal conditions was performed on the full system. Beam delivery testing evaluated the following:

1. Creation and direction the proton beam appropriately to the patient treatment location;
2. Production of a transverse and longitudinal distribution appropriate for the patient treatment; and
3. Delivery of the designated dose to the patient's treatment site.

Testing to evaluate electrical safety and electromagnetic compatibility was performed in accordance with IEC 60601-1 and IEC 60601-1-2, and a usability evaluation was conducted to confirm that users can interact with the system user interface to perform treatment with the device system.

All testing demonstrated that the system met its specifications for its intended use.

Substantial Equivalence

The ProTom Radiance 330™ has the same intended use and similar indications, principles of operation, and technological characteristics as the Ion Beam Applications Proton Therapy System with PPBS (K082416), Hitachi Ltd.'s PROBEAT with DSSS (K073059); and the Loma Linda Optivus Technology Proton Beam Therapy System (K992414). The minor differences between the Radiance 330™ and the predicate devices do not raise any new questions of safety or effectiveness. Performance data demonstrates that the Radiance 330™ is as safe and effective as the predicate devices. Thus, the ProTom Radiance 330™ is substantially equivalent to its predicates.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WQ66-G609
Silver Spring, MD 20993-0002

ProTom International, Inc.
% John J. Smith, MD, JD, Partner
Hogan Lovells US LLP
555 13th Street, NW
WASHINGTON DC 20001

March 14, 2014

Re: K134052

Trade/Device Name: Radiance 330[®] Proton Therapy System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: December 31, 2013
Received: December 31, 2013

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

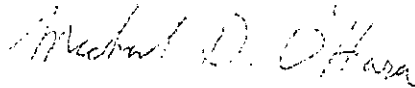
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Michael D. O'Hara". The signature is written in a cursive, slightly slanted style.

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K134052

Device Name: Radiance 330® Proton Therapy System

Indications For Use:

The ProTom Radiance 330 is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.

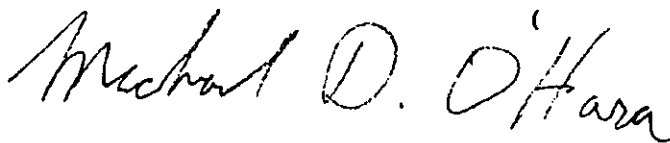
Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)



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(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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